

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

CIVIL ACTION NO. 07-12389-RGS

BIO-MIMETICS, INC.

v.

COLUMBIA LABORATORIES, INC.

ORDER ON MOTION FOR
RECONSIDERATION OF ORDER ON MOTION
FOR CLARIFICATION

May 26, 2010

STEARNS, D.J.

On March 31, 2010, the court issued a Memorandum and Order on the parties' cross-motions for summary judgment on Bio-Mimetics' claims of breach of contract, correction of inventorship pursuant to 35 U.S.C. § 256, and unfair and deceptive trade practices. On April 9, 2010, Bio-Mimetics filed a motion for clarification, which the court denied on April 16, 2010. Also on April 16, 2010, Bio-Mimetics filed a motion for reconsideration of the order on the motion for clarification. Columbia Laboratories (Columbia) opposes the motion.

At issue in this litigation is a drug delivery system (BDS technology) that uses an application of a class of cross-linked polymers (notably, polycarbophil) as bioadhesive delivery agents. For a number of years, Columbia paid royalties to Bio-Mimetics for sales of CRINONE and STRIANT, products that practiced claims contained in U.S. Patent No. 4,615,697 ('697 patent). The '697 patent expired on October 7, 2003. Its last foreign

equivalent patent expired on September 26, 2006. At that point, Columbia ceased paying royalties based on sales of CRINONE and STRIANT.

In the course of the summary judgment briefing, Bio-Mimetics argued that Columbia's royalty obligations on CRINONE and STRIANT endured until a cumulative total of \$7.5 million had been paid. Columbia, on the other hand, argued that the obligations were extinguished when the last of the foreign patents related to the '697 patent expired.

After review of the parties' "Asset Purchase, License and Option Agreement" (Agreement), the court rejected both parties' interpretations. The court ruled that

[t]he Agreement provides that it

shall terminate upon the **earlier of** (a) the payment by [Columbia] to [Bio-Mimetics] of the Purchase Royalty Maximum and License Royalty Maximum [\$7.5 million] or (b)[i] the expiration or declared invalidity of **all** Patents covered by this Agreement, or [ii] fifteen (15) years, whichever is later. Agreement, ¶ 7 (emphasis added). As the plain language of Paragraph 7 states, Columbia is not unconditionally obligated to make payments until the \$7.5 million amount is reached. If, before that happens, **all** of the patents covered by the Agreement are found invalid or have expired, Columbia's payment obligations cease.

Memorandum and Order at 6 (emphasis added).¹ The court then turned to the question of whether the patents covering CRINONE and STRIANT were "improvements" on the '697 patent, as the Agreement provides that any "improvement" is to be automatically added to Schedule 2 and "provide an ongoing basis" for the payment of royalties. Agreement ¶ 2. The court held that "the determination of whether or not CRINONE and STRIANT are

¹The court additionally noted that because the fifteen-year term referenced in (b)(ii) expired in 2004, it was no longer relevant. *Id.* n. 7.

founded on the BDS technology is a matter for the jury to resolve.” Memorandum and Order at 10.

On April 9, 2010, Bio-Mimetics moved for clarification, arguing that because it is undisputed that CRINONE and STRIANT are “based on” technology that is subject to the Agreement, Columbia remains obligated to make royalty payments. The court denied the motion, reiterating its conclusion that “[t]he issue of whether the patents related to Crinone and Striant are ‘covered’ by the parties’ Agreement – i.e., whether they represent improvements upon the BDS technology – is for the jury’s determination.” Electronic Order, April 16, 2010.

On the same day, Bio-Mimetics filed a motion for reconsideration in which it refined its argument with regard to the motion for clarification. Bio-Mimetics now contends that because not all of the patents covered by the Agreement have expired (or been found invalid), there is no present need to have a jury determine whether CRINONE and STRIANT are “improvements” on the ‘697 patent. Specifically, Bio-Mimetics notes that because U.S. Patent No. 5,474,768 (‘768 patent), which was indisputably part of Schedule 2, does not expire until 2013, the Agreement remains in force and Columbia’s obligation to pay royalties on CRINONE and STRIANT remains in force. Columbia vigorously objects to Bio-Mimetics’ motion, arguing that to entertain Bio-Mimetics’ refinement of its position would rescind the effect of the court’s previous ruling denying partial summary judgment.

DISCUSSION

Columbia bases its opposition on Paragraph 2 of the Agreement, which states that the obligation to pay license royalties exists only during the life of the patent(s) tied specifically to the product(s) in question. Columbia argues that

[a]s discussed in the Court's opinion, Paragraph 2 creates . . . an express license royalty condition – i.e., “the obligation to pay royalties with respect to products covered by the License shall be coterminous with the life of the patent(s) which are specific to each product[.]” (Agreement ¶ 2). This license royalty condition remained in effect after Columbia exercised the option. Paragraph 6 addresses this point directly: “If the Option is exercised, there shall remain due and owing to Seller, in the form of installment purchase payments . . . , *amounts exactly equal to and payable on the same conditions and in the same manner as*” the license royalty obligations in effect before the option was exercised. Agreement ¶ 6 (emphasis added).

Opp'n at 7.

Columbia, however, misconstrues the court's prior ruling. The court specifically held that Paragraph 2 of the Agreement no longer applies.

Columbia argues that Paragraph 7 of the Agreement is superseded by Paragraph 2, which provides that “[t]he term of the License and/or the obligation to pay royalties with respect to products covered by the License shall be coterminous with the life of the patent(s) which are specific to each such product, or fifteen (15) years, whichever is longer.” *Id.* ¶ 2. Columbia reasons that because the '697 patent has expired, no further “royalties” are due. *The court, however, agrees with Bio-Mimetics that Paragraph [2] applies only to the License, which became obsolete in 1991, when Columbia exercised the Option to purchase the Two-Thirds Interest. As the only issue here is the Asset Purchase Agreement, Paragraph 7 controls.*

Memorandum and Order at 6-7 (emphasis added).² In addition, the court specifically held that the obligation to pay the “royalty equivalents” in the form of installment purchase payments is not tied directly to the life of a patent.

²Although the court found the portion of Paragraph 2 dealing with the License to be irrelevant, the portion of Paragraph 2 that sets forth the technology to be included in Schedule 2 remains valid.

The determination does not offend the principle stated in Brulotte v. Thys Co., 379 U.S. 30, 32 (1964), that a patent owner cannot by private contract extend the statutory life of a patent. In this case, the payments owed by Columbia are not royalties in any conventional sense, given that Columbia exercised the Option to purchase all of Bio-Mimetics' remaining assets. Instead, the payments are more appropriately characterized as "installment purchase payments." As Judge Saris has explained, "royalties in an assignment agreement are properly conceived as deferred consideration for the original conveyance of rights, with the amount of consideration pegged to the commercial success of the product." Baladevon, Inc. v. Abbott Labs., Inc., 871 F. Supp. 89, 96 (D. Mass. 1994).

Memorandum and Order at 7 n.8.

Moreover, Paragraph 6 does not state that Columbia's obligation to pay royalties is coextensive with the life of the patent(s) tied to a product. Rather, Paragraph 6 states, in pertinent part, that

[i]f the Option is exercised, there shall remain due and owing to Seller, in the form of the **installment purchase payments** in consideration of the transfer of the Two-Thirds Interest, amounts exactly equal to and payable on the same conditions and in the same manner as the License Royalty Maximum provided for in subparagraph 3(b).

Agreement, ¶ 6 (emphasis added).³ Paragraph 3(b), in turn, provides in pertinent part only that Columbia was required to pay royalties for

the sale of products based on the Purchased Assets or the Two-Thirds Interest. . . . [i]f the Option is exercised, Buyer shall continue to pay royalty equivalents to Seller with respect to the Two-Thirds Interest, subject to the License Royalty Maximum, as further set forth in Paragraph 6.

Id. ¶ 3(b) (emphasis added). It is clear that Paragraphs 3 and 6 require royalties to be paid for all products "based on" the Two-Thirds Interest, with no requirement that the payments be tied to specific patents.

³Contrary to Columbia's suggestion, no mention is made of Paragraph 2, which in any event the court has already held applies only to the defunct License.

Although the court noted the '768 patent in passing, see Memorandum and Order at 2, n.4, it did not factor the '768 patent into its consideration of the parties' arguments at the summary judgment stage. As Bio-Mimetics notes, because the parties each offered differing interpretations of the Agreement, both of which the court ultimately rejected, "neither party had squarely addressed what consequences would flow from the Court's interpretation of the Agreement, which differed from what either party had proposed. Thus, the Court did not have the occasion to address how its ruling would affect Columbia's payment obligations." Reply at 1.

Consistent with its summary judgment ruling setting the parameters of Columbia's obligations, the court now finds that because the '768 patent remains valid and unexpired, Columbia is obligated to continue to pay royalty equivalents/installment purchase payments on the sales of CRINONE and STRIANT.

CONCLUSION

For the foregoing reasons, Bio-Mimetics' motion for reconsideration is ALLOWED. The court's ruling obviates any present need for a trial on the issue of whether the patents related to CRINONE and STRIANT constitute "improvements" on the BDS technology. The parties' joint motion to postpone the trial date will therefore be TERMINATED as moot and the Clerk will close the case.

SO ORDERED.

/s/ Richard G. Stearns

UNITED STATES DISTRICT JUDGE